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3.0 Summary of Safety and Effectiveness Information [510(k) Summary]

SPONSOR:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700 Contact: Lisa M. Boyle
DEVICE NAME:	Synthes (USA) Titanium Wire
CLASSIFICATION:	Class II § 21 CFR 878.4495: Stainless Steel
PREDICATE DEVICE:	Ethicon Inc.: Ethilon™ Nylon Sutures
DEVICE DESCRIPTION:	The Synthes Titanium Wire is a nonabsorbable, monofilament, sterile surgical wire composed of Commercially Pure Titanium. The titanium wire is available in a length of 500mm with different gauge sizes and is available with or without a permanently attached stainless steel needle.
INTENDED USE:	Synthes (USA) Titanium Wire is indicated for use in soft tissue approximation and/or ligation, for canthoplasty, canthopexy and/or canthal tendon repair.
SUBSTANTIAL EQUIVALENCE:	Comparative information presented supports substantial equivalence. The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

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4.0 Device Name

Synthes (USA) [Synthes] Titanium Wire

5.0 Establishment Registration

The devices subject to this Pre-market Notification will be distributed by Synthes (USA), 1101 Synthes Avenue, Monument, CO 80312 (FDA Registration No. 1719045) and manufactured by Unique Instruments, Inc. 6688 Dixie Highway, Bridgeport, MI 48722 (FDA Registration No. 1828288).

6.0 Classification Information

The classification of the Synthes Titanium Wire has been determined to be Class II, as per Title 21 of the Code of Federal Regulations, section : 878.5020: Suture, Nonabsorbable, Synthetic, Polyamide.

7.0 Information Relating to Performance Standards and Special Controls

The material used in the manufacture of the Synthes Titanium Wire is Commercially Pure (CP) Titanium, which adheres to American Society for Testing and Materials (ASTM) standards [F-1341].

8.0 Sterilization Information

Synthes will provide these devices STERILE. Information supporting the sterile device can be found in **Attachment 1**. These devices are for single use only.

9.0 Description of the Device

The Synthes Titanium Wire is a non-absorbable, monofilament, sterile surgical wire composed of Commercially Pure Titanium. The titanium wire is available in a length of 500mm with different gauge sizes (26, 28, 30, 32) and is available with or without a permanently attached stainless steel needle.

Confidential engineering drawings can be found in Attachment II.

10.0 Proposed Labels/Labeling

Please see Attachment III.

11.0 Commercially Available Device Information

The predicate device, Ethicon's Ethilon Nylon Suture, has been cleared for commercial distribution via the premarket notification process. Information on the predicate device can be found in Attachment IV.

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12.0 Comparison to Commercially Available Device(s)

A comparison of the Synthes Titanium Wire to the predicate Ethilon™ Nylon Suture is below:

Device Comparison Chart

New Device **Synthes Titanium Wire**	**Predicate Device** **Ethicon, Inc.** **Ethilon™ Nylon Suture** 510(k) Unknown
Indications: Synthes (USA) Titanium Wire is indicated for use in general soft tissue approximation and /or ligation, including use in ophthalmic procedures, such as canthoplasty.	**Indications:** ETHILON suture is indicated for use in general soft tissue approximation, and / or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Design Features: • Monofilament • Sterile • Nonabsorbable • Available with or without needle	**Design Features:** • Monofilament • Sterile • Nonabsorbable • Available with or without needle
Dimensions (mm): Sizes: • Diameter: 0.20, 0.25, 0.31, 0.40 (26, 28, 30 & 32 gauge) • Length: 500	**Dimensions (mm):** Sizes: • Diameter: 0.01 - 0.5 • Length: Various
Material: Titanium	**Material:** Nylon

13.0 Determination of Substantial Equivalence: [ref. Office of Device Evaluation (ODE) Blue Book Memorandum #86-3, Attachment I "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)"]

New Device [Synthes (USA) Titanium Wire] **is Compared to Marketed Device** [Ethicon: Ethilon Nylon Suture].

Does New Device Have Same Indication Statements? Essentially yes. Both devices are indicated for soft tissue approximation and/or ligation; however the Titanium Wire has a more specific indication to include canthoplasty.

New Device Has Same Intended Use and May be "Substantially Equivalent".

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?
Design: Yes. The design of the Titanium Wire is similar to the predicate device in that it is a nonabsorbable, monofilament wire which is available in a range of diameters/gauge sizes with or without attached needle. The subject device is 500 mm in length and provided sterile only.

Materials: No. The Synthes Titanium Wire is manufactured from CP Titanium where as, the predicate device is manufactured from Nylon.

Could the New Characteristics Affect Safety or Effectiveness? No.
To establish the technical equivalency of the Synthes Titanium Wire to the predicate device, tests according to methods presented in United States Pharmacopia (U.S.P.) were conducted for titanium wire with and without needle. The test results show that the Synthes titanium wire tested met USP standards for length, tensile strength, and needle attachment strength, not diameter, and are technically equivalent to the predicate device tested. Please see the attached mechanical test summary, which can be found in Attachment V.

14.0 Confidentiality Certification

We consider our intent to market this device to be confidential commercial information. Synthes has not disclosed the intent to market this product to others who are not collaborators and consultants. We have taken caution to protect the confidentiality of our intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K041333
Trade/Device Name: Synthes (USA) Titanium Wire
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: July 26, 2004
Received: July 27, 2004

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K041333

Device Name: Synthes (USA) Titanium Wire

Indications:

Synthes (USA) Titanium Wire is indicated for use in soft tissue approximation and/or ligation, for canthoplasty, canthopexy and/or canthal tendon repair.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041333